ABSTRACT

HPLC EVALUATION OF TRANSKARBAM AND ITS IMPURITIES II

Rigorózní práce

Mgr. Kateřina Strašilová

Charles University in Prague, Fakulty of Pharmacy in Hradec Králové, Department of Pharmaceutical Chemistry and Drug Control, Heyrovského 1203, Hradec Králové

This work deals with determination of 6-aminohexanoic acid in ointment-base by high performance liquid chromatography with subsequent validation of chromatographic conditions. 6-aminohexanoic acid is one of two main predicted degradation products of transkarbam 12, functioning as an enhancer of transdermal penetration. A pre-column derivatization with 3,5-dinitrobenzoylchloride forerun the quantification of 6-aminohexanoic acid. The analysis was run on the reversed-phase column Separon SGX C-18 (150 x 3 mm I.D., 5 μm) with gradient elution of mobile phase composed of acetonitrile and sodium acetate buffer (20 mM, pH 4,5) with the flow rate 1 ml/min. UV detection was performed at 230 nm. The validation parametres such as precision and accuracy, linearity, selectivity, robustness and limit of detection and limit of quantification were evaluated.